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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,370

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7590 10/07/2009
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EXAMINER

WITCZAK, CATHERINE

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

10/07/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/791,370	Applicant(s) MICHELS ET AL.	
	Examiner CATHERINE N. WITCZAK	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/23/06; 6/15/05; 6/4/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claim 42 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/5/2009.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3-7, 21-24, and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Peters (US 6,508,807).

Peters discloses a device comprising a first catheter (5) having one end (10) received within the end (21) of a second catheter (2) in an overlap area; a collar (15) with a first opening (42) for encircling the first catheter which is smaller than a second opening (44) for encircling a second catheter, the collar surrounding a portion of the overlap; a clamp (30) encircling a recessed area on the collar and the overlap area; the clamp having a pair of spaced jaws (31/32) and a tongue (48) having teeth to interlock with teeth (49) on the first jaw (31); the diameter of a distal cavity of the collar (from 42) being smaller than the diameter of proximal cavity of the collar (44).

Claim Rejections - 35 USC § 103

Art Unit: 3767

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-10 and 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin (US 4,895,570) as modified by Peters.

Larkin discloses a device comprising a first catheter (18) having one end (20) received within the end of a second catheter (12) in an overlap area; a collar (28) with a first opening for encircling the first catheter which is smaller than a second opening for encircling a second catheter (Figure 2), the collar surrounding a portion of the overlap; the diameter of a distal cavity of the collar being smaller than the diameter of proximal cavity of the collar (Figure 2); and a collet (22) having a ring portion (48) from which panels (26) extend

Larkin discloses the claimed device except for a clamp encircling the collar and overlap area; the clamp having a pair of spaced jaws and a tongue having teeth to interlock with teeth on the first jaw. Peters discloses in Figure 4 that it is known to use a clamp with jaws and teeth. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Larkin with a clamp as taught by Peters since such a modification would provide additional security and protection against infection when connecting two medical tubes to each other.

3. Claims 2, 11-20, 28-30 and 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin as modified by Peters in further view of Glantz (US 5,558,641).

Larkin as modified by Peters discloses the claimed device except for the device being used to establish fluid communication in a system comprising a reservoir having a pierceable septum and outlet tube configured to be received within one end of the second catheter in fluid communication with the

Art Unit: 3767

reservoir. Glantz et al disclose in Figure 5 that it is known to use catheter connector devices in implantable pump systems. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Larkin as modified by Peters with the teachings of Glantz et al since it is routine practice in the medical art to employ catheter connectors in implantable pump systems such as the one disclosed by Glantz, with the incorporation of the features of the device of Larkin as modified by Peters providing for an implantable pump system with a secure system for preventing the disconnection of the catheter components and thus minimizing risk to patients.

Larkin as modified by Peters disclose the claimed device except for the connector also comprising a sleeve having a flared lip extending from the first portion to surround a portion of the first catheter; the sleeve portion being about 2-6 inches long and having an outer diameter at least about 50% larger than the first catheter outer diameter. Glantz et al disclose in Figures 13 that it is known to use catheter connector devices in which a portion of a first catheter is surrounded by a sleeve having a lip which extends from the connector structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Larkin as modified by Peters with the teachings of Glantz et al since the incorporation of a sleeve would add support to the first catheter, thus reducing the risk of kinking of the catheter or disconnection from the connector. Although Glantz et al do not expressly disclose the length or diameter of the sleeve portion, it is routine practice in the medical art to vary the sizes of device components depending on the particular use of the device, and thus it would have been obvious to one having ordinary skill in the art to modify the dimensions of the sleeve to match those claimed in claims 12-14, 17-19, 29, 33 and 34.

Art Unit: 3767

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE N. WITCZAK whose telephone number is (571)272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Catherine N Witczak/

Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767